

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Application No. : 09/867,235
Applicant(s) : L. R. Robinson et al.
Filed : 05/29/2001
Title : Methods of Enhancing Delivery of Oil-Soluble Skin Care
Actives
TC/A.U. : 1617
Examiner : San-ming Hui
Conf. No. : 5928
Docket No. : 8569
Customer No. : 27752

BRIEF ON APPEALS

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450


Dear Sir:

Enclosed, pursuant to 37 C.F.R. 1.192(a), is Appellant's brief on Appeal for the above application.

The fee for this Brief on Appeal is \$500.00 37 CFR 1.17(c).

The Director is hereby authorized to charge the above fee, or any additional fees that may be required, or credit any overpayment to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
THE PROCTER & GAMBLE COMPANY

By 
Juliet A. Jones
Registration No. 54,202
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May 13, 2005
Customer No. 27752

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Filed : 05/29/2001
Title : Methods of Enhancing Delivery of Oil-Soluble Skin
Care
Actives
TC/A.U. : 1617
Examiner : Lauren Q. Wells
Conf. No. : 5928
Docket No. : 8569

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

This Appeal Brief is submitted in support of the Notice of Appeal transmitted to the PTO via facsimile on March 14, 2005, which set a two-month period for response.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

STATUS OF CLAIMS

Claims 27-31 are pending in the present application. Claims 1-26 have been previously withdrawn. Claims 27-31 are appealed. A complete copy of the appealed claims is set forth in the Claims Appendix.

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STATUS OF AMENDMENTS

No amendment was filed.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to a method of enhancing the delivery of oil-soluble skin care actives into skin, comprising applying to the skin of a mammal in need of treatment a safe and effective amount of a water-in-oil composition consisting essentially of an oil soluble skin care active, a silicone oil, and a silicone elastomer. The oil soluble skin care active is selected from the group consisting of terpene alcohols, oil-soluble phytosterols, oil-soluble anti-acne actives, oil-soluble beta-hydroxy acids, oil-soluble vitamin B₃ compounds, oil-soluble retinoids, oil-soluble anti-oxidants, oil-soluble radical scavengers, oil-soluble chelators, oil-soluble flavonoids, oil-soluble anti-inflammatory agents, oil-soluble anti-cellulite agents, oil-soluble topical anesthetics, and mixtures thereof. The skin care active is delivered into the skin in order to impart positive skin care benefits. See specification page 2, lines 28-33 through page 3, lines 1 – 2, and also page 4, lines 31-32.

The present invention further relates to a method of enhancing the delivery of oil soluble skin care actives into the skin from the oil phase of a topical water-in-oil emulsion composition. The method comprises applying said topical composition to the skin, wherein the topical composition's oil phase consists essentially of a silicone elastomer; and an oil soluble skin care active. The oil soluble skin care active is selected from the group consisting of terpene alcohols, oil-soluble phytosterols, oil-soluble anti-acne actives, oil-soluble beta-hydroxy acids, oil-soluble vitamin B₃ compounds, oil-soluble retinoids, oil-soluble anti-oxidants, oil-soluble radical scavengers, oil-soluble chelators, oil-soluble flavonoids, oil-soluble anti-inflammatory agents, oil-soluble anti-cellulite agents, oil-soluble topical anesthetics, and mixtures thereof. The skin care active is delivered into the skin in order to impart positive skin care benefits. See specification page 2, lines 28-33 through page 3, lines 1 – 2, and also page 6, lines 3-6.

The present invention further relates to a method of regulating the condition of skin. The method comprises the step of topically applying to the skin of a mammal in

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need of treatment, a safe and effective amount of the composition comprising an oil continuous phase and an aqueous discontinuous phase. The oil phase consists essentially of an oil soluble skin care active, a silicone oil, and a silicone elastomer. The skin care active is selected from the group consisting of terpene alcohols, oil-soluble phytosterols, oil-soluble anti-acne actives, oil-soluble beta-hydroxy acids, oil-soluble vitamin B₃ compounds, oil-soluble retinoids, oil-soluble anti-oxidants, oil-soluble radical scavengers, oil-soluble chelators, oil-soluble flavonoids, oil-soluble anti-inflammatory agents, oil-soluble anti-cellulite agents, oil-soluble topical anesthetics, and mixtures thereof. The skin care active is delivered into the skin in order to impart positive skin care benefits. See specification page 2, lines 28-33 through page 3, lines 1 – 2, and also page 6, lines 13-15.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Rejection under 35 U.S.C. 102(b) over EP 0,908,175 (Rouquet et al.).

ARGUMENTS

I. The rejection under 35 U.S.C. 102(b) is improper, as the reference does not anticipate all elements of Applicants' claimed invention.

The Examiner asserts that the '175 reference (Rouquet et al.) teaches application to the skin of compositions containing the same components as Applicants' invention, which would inherently enhance the delivery of the oil soluble skin care active. The Examiner further asserts that Applicants have not provided any evidence of record to show that the prior art compositions do not exhibit the same properties as the instantly claimed compositions.

To establish a prima facie case of anticipation or obviousness, the claimed invention and the prior art must be identical or substantially identical. M.P.E.P. 2112.01. Applicants assert that for the following reasons, Applicants' invention is not identical to, and thus not anticipated by, the '175 reference.

The '175 reference teaches that the compositions may comprise skin care actives, including vitamins such as tocopherols (vitamin E), vitamin A, and vitamin C. See page 8, paragraph [0033] of Rouquet. Of the numerous vitamins known in the art, Applicants

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claim only oil-soluble vitamin B3 compounds. The '175 reference makes a broad reference to antioxidants. Of the literally thousands of anti-oxidants known in the art, Applicants claim only oil-soluble anti-oxidants. The remaining actives claimed by Applicants also do not appear to be taught. Furthermore, Applicants' claims are directed toward enhanced delivery of only oil-soluble actives into the skin. The '175 reference fails to teach delivery of actives into the skin, and makes no distinction between water-soluble and oil-soluble actives. In fact, the '175 reference explicitly teaches actives, for example sunscreens, that are effective only on the surface of the skin.

Because the '175 reference does not specifically disclose or contemplate all elements of Applicants' compositions, Applicants respectfully submit that the rejection under 35 U.S.C. 102(b) is improper.

II. To the extent that overlap of subject matter exists, Applicants' claims represent a patentable sub-class of the general disclosure in the '175 reference.

Assuming, *arguendo*, that overlap does exist between Applicants' claims and the '175 disclosure, Applicants assert that the oil-soluble actives of the present invention represent a patentable sub-class of the '175 reference's broad disclosure of actives. The Federal Circuit has addressed the issue of allowing claims relating to sub-classes of chemical compounds over a broad disclosure in the prior art, and held that such disclosure does not necessarily preclude patenting of sub-classes or individual compounds. In *Ex parte Westphal*, the Board stated:

It has specifically been held that the disclosure of a genus and a species of a subgenus within that genus is not sufficient description of the subgenus to comply with the description requirement of 35 U.S.C. 112, unless there are specific facts which lead to a determination that a subgenus is implicitly described.

26 U.S.P.Q.2d 1858,1860 (B.P.A.I. 1992). See also *In re Baird*, 16 F.3d 380, 383, 29 U.S.P.Q.2D (BNA) 1550, 1553 (Fed. Cir. 1994), and *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2D (BNA) 1941 (Fed. Cir. 1992).

Whereas the instant claims are not directed literally toward a species, the concept is similar: Oil-soluble vitamins, anti-oxidants and other actives are a distinct subclass of the general class of vitamins, anti-oxidants and other actives. Applicants have found that

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delivery of oil soluble actives into the skin is enhanced relative to water-soluble actives, and have data in the record to support this finding in the form of a declaration under 37 CFR §1.132, submitted on September 20, 2004. This data was submitted in response to the Office Action of April 21, 2004, which, in also rejecting the instant claims under 35 U.S.C. 102(b) over Rouquet et al., asserted that Applicants had provided no data to show unexpected results. Although Applicants are aware that declarations under 37 CFR §1.132 typically are submitted to overcome a rejection under 35 U.S.C. 103 rather than 102, Applicants nevertheless provided this data. A subsequent Examiner upheld the rejection in the Office Action of December 14, 2004, on the basis that unexpected results are insufficient to overcome an anticipation rejection. Applicants maintain, however, that the data in the declaration clearly distinguishes the subclass of oil-soluble actives over the more general class of vitamins and anti-oxidants, and provides support for Applicants' claims.

III. Applicants' data shows that the prior art compositions may not exhibit the same properties as instantly claimed.

The Office Action asserts the burden is shifted to Applicants to show that the compositions taught in the '175 reference do not inherently possess the properties of Applicants' claimed compositions. Assuming, *arguendo*, that this shifting of the burden of proof is proper, Applicants have provided such evidence in the aforementioned declaration, and therefore respectfully submit that the Office Action's assertion that "Applicant[s] have provided no evidence showing that the prior art compositions do not exhibit the same properties as instantly claimed," is in error.

The '175 reference teaches compositions comprising skin care actives, and fails to distinguish between oil-soluble and water-soluble actives. The reference further teaches actives that are more effective on the surface of the skin. Therefore, the compositions of the '175 reference would not necessarily result in compositions that enhance delivery of *oil-soluble* actives *into* the skin. In contrast, Applicants' data show that when oil-soluble actives are chosen, the delivery thereof into the skin is clearly enhanced. Therefore, Applicants have provided evidence that the '175 compositions may not exhibit the same properties as claimed in the present invention.

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SUMMARY

In light of the arguments set forth above, it is respectfully submitted that the rejection under 35 U.S.C. 102(b) is improper. Applicants respectfully request reversal of the rejection of claims 27-31.

Respectfully submitted,
THE PROCTER & GAMBLE COMPANY



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CLAIMS APPENDIX

Claims 1-26 (Canceled)

27. (Rejected) A method of enhancing the delivery of oil-soluble skin care actives into the skin comprising applying to the skin of a mammal in need of treatment, a safe and effective amount of a water-in-oil composition consisting essentially of:

- a) an oil soluble skin care active, selected from the group consisting of terpene alcohols, oil-soluble phytosterols, oil-soluble anti-acne actives, oil-soluble beta-hydroxy acids, oil-soluble vitamin B₃ compounds, oil-soluble retinoids, oil-soluble anti-oxidants, oil-soluble radical scavengers, oil-soluble chelators, oil-soluble flavonoids, oil-soluble anti-inflammatory agents, oil-soluble anti-cellulite agents, oil-soluble topical anesthetics, and mixtures thereof, wherein said skin care active is delivered into the skin in order to impart positive skin care benefits;
- b) a silicone oil; and
- c) a silicone elastomer,

28. (Rejected) A method of enhancing the delivery of oil soluble skin care actives into the skin according to claim 27 wherein the composition's oil continuous phase consists essentially of:

- a) an oil soluble skin care active, selected from the group consisting of terpene alcohols, oil-soluble phytosterols, oil-soluble anti-acne actives, oil-soluble beta-hydroxy acids, oil-soluble vitamin B₃ compounds, oil-soluble retinoids, oil-soluble anti-oxidants, oil-soluble radical scavengers, oil-soluble chelators, oil-soluble flavonoids, oil-soluble anti-inflammatory agents, oil-soluble anti-cellulite agents, oil-soluble topical anesthetics, and mixtures thereof, wherein said skin care active is delivered into the skin in order to impart positive skin care benefits;
- b) a silicone oil; and
- c) a silicone elastomer.

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29. (Rejected) A method of enhancing the delivery of oil soluble skin care actives into the skin from the oil phase of a topical water-in-oil emulsion composition comprising, applying said topical composition to the skin, said topical composition's oil phase consisting essentially of:

- i) a silicone elastomer; and
- ii) an oil soluble skin care active, selected from the group consisting of terpene alcohols, oil-soluble phytosterols, oil-soluble anti-acne actives, oil-soluble beta-hydroxy acids, oil-soluble vitamin B₃ compounds, oil-soluble retinoids, oil-soluble anti-oxidants, oil-soluble radical scavengers, oil-soluble chelators, oil-soluble flavonoids, oil-soluble anti-inflammatory agents, oil-soluble anti-cellulite agents, oil-soluble topical anesthetics, and mixtures thereof, wherein said skin care active is delivered into the skin in order to impart positive skin care benefits.

30. (Rejected) A method of regulating the condition of skin, said method comprising the step of topically applying to the skin of mammal in need of treatment, a safe and effective amount of the composition comprising an oil continuous phase and an aqueous discontinuous phase wherein the oil phase consists essentially of:

- a) an oil soluble skin care active, selected from the group consisting of terpene alcohols, oil-soluble phytosterols, oil-soluble anti-acne actives, oil-soluble beta-hydroxy acids, oil-soluble vitamin B₃ compounds, oil-soluble retinoids, oil-soluble anti-oxidants, oil-soluble radical scavengers, oil-soluble chelators, oil-soluble flavonoids, oil-soluble anti-inflammatory agents, oil-soluble anti-cellulite agents, oil-soluble topical anesthetics, and mixtures thereof, wherein said skin care active is delivered into the skin in order to impart positive skin care benefits;
- b) a silicone oil; and
- c) a silicone elastomer.

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31. (Rejected) The method according to claim 30 wherein the composition comprises an oil continuous phase and an aqueous discontinuous phase, wherein the oil phase consists essentially of;

- a) an oil soluble skin care active, selected from the group consisting of terpene alcohols, oil-soluble phytosterols, oil-soluble anti-acne actives, oil-soluble beta-hydroxy acids, oil-soluble vitamin B₃ compounds, oil-soluble retinoids, oil-soluble anti-oxidants, oil-soluble radical scavengers, oil-soluble chelators, oil-soluble flavonoids, oil-soluble anti-inflammatory agents, oil-soluble anti-cellulite agents, oil-soluble topical anesthetics, and mixtures thereof, wherein said skin care active is delivered into the skin in order to impart positive skin care benefits;
- b) a silicone oil; and
- c) a silicone elastomer.

Procter & Gamble - Intellectual Property Division**IMPORTANT CONFIDENTIALITY NOTICE**

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Phone No. (571)-272-0626

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on May 13, 2005, to the above-identified facsimile number.

 (Signature)

**FROM: Juliet A. Jones
Fax No. (513) 626-1355
Phone No. (513) 626-2127**

Listed below are the item(s) being submitted with this Certificate of Transmission:

- 1) Transmittal for Appeal Brief, and one copy for authorization to charge fee to Deposit Account;
- 2) Appeal Brief (9 pages);

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